

**§ 84.33 Approval labels and markings; approval of contents; use.**

(a) Full-scale reproductions of approval labels and markings, and a sketch or description of the method of application and position on the harness, container, canister, cartridge, filter, or other component, together with instructions for the use and maintenance of the respirator shall be submitted to the Institute for approval.

(b) Approval labels shall bear the emblem of the National Institute for Occupational Safety and Health and the seal of the Department of Health and Human Services, the applicant's name and address, an approval number assigned by the Institute and, where ap-

propriate, restrictions or limitations placed upon the use of the respirator by the Institute. The approval number assigned by the Institute shall be designated by the prefix TC and a serial number.

(c) The Institute shall, where necessary, notify the applicant when additional labels, markings, or instructions will be required.

(d) Approval labels and markings shall only be used by the applicant to whom they were issued.

(e) Legible reproductions or abbreviated forms of the label approved by the Institute for use on each respirator shall be attached to or printed at the following locations:

Respirator type	Label type	Location
Self-contained breathing apparatus.	Entire .....	Harness assembly and canister (where applicable).
Gas mask .....	Entire .....	Mask container and canister.
Supplied air respirator .....	.....do .....	Respirator container or instruction card.
Particulate respirator .....	.....do .....	Respirator container and filter container.
	Abbreviated .....	Filters.
Chemical-cartridge respirator ...	Entire .....	Respirator container, cartridge container, and filter containers (where applicable).
	Abbreviated .....	Cartridges and filters and filter containers.

(f) The use of any Institute approval label obligates the applicant to whom it is issued to maintain or cause to be maintained the approved quality control sampling schedule and the acceptable quality level for each characteristic tested, and to assure that it is manufactured according to the drawings and specifications upon which the certificate of approval is based.

(g) Each respirator, respirator component, and respirator container shall, as required by the Institute to assure quality control and proper use of the respirator, be labeled distinctly to show the name of the applicant, and the name and letters or numbers by which the respirator or respirator component is designated for trade purposes, and the lot number, serial number, or approximate date of manufacture.

**§ 84.34 Revocation of certificates of approval.**

The Institute reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part. Such causes include,

but are not limited to, misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval.

**§ 84.35 Changes or modifications of approved respirators; issuance of modification of certificate of approval.**

(a) Each applicant may, if he desires to change any feature of an approved respirator, request a modification of the original certificate of approval issued by the Institute for such respirator by filing an application for such modification in accordance with the provisions of this section.

(b) Applications shall be submitted as for an original certificate of approval, with a request for a modification of the existing certificate to cover any proposed change.

(c) The application shall be accompanied by appropriate drawings and specifications, and by a proposed quality control plan which meets the requirements of subpart E of this part.

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(d) The application for modification, together with the accompanying material, shall be examined by the Institute to determine whether testing will be required.

(e) The Institute shall inform the applicant of the fee required for any additional testing and the applicant will be charged for the actual cost of any examination, inspection, or test required, and such fees shall be submitted in accordance with the provisions of subpart C of this part.

(f) If the proposed change or modification meets the requirements of this part, a formal certificate of modification will be issued, accompanied, where necessary, by a list of new and revised drawings and specifications covering the change(s) and reproductions of revised approval labels.

(The information collections contained in this section are approved under OMB control number 0920-0109)

### § 84.36 Delivery of changed or modified approved respirator.

An approved respirator for which a formal certificate of modification has been issued shall be delivered, with proper markings and containers, by the applicant to the Certification and Quality Assurance Branch, as soon as it is commercially produced.

## Subpart E—Quality Control

### § 84.40 Quality control plans; filing requirements.

As a part of each application for approval or modification of approval submitted pursuant to this part, each applicant shall file with the Institute a proposed quality control plan which shall be designed to assure the quality of respiratory protection provided by the respirator for which approval is sought.

#### § 84.41 Quality control plans; contents.

(a) Each quality control plan shall contain provisions for the management of quality, including:

(1) Requirements for the production of quality data and the use of quality control records;

(2) Control of engineering drawings, documentations, and changes;

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(3) Control and calibration of measuring and test equipment;

(4) Control of purchased material to include incoming inspection;

(5) Lot identification, control of processes, manufacturing, fabrication, and assembly work conducted in the applicant's plant;

(6) Audit of final inspection of the completed product; and

(7) The organizational structure necessary to carry out these provisions.

(b) Each provision for incoming and final inspection in the quality control plan shall include a procedure for the selection of a sample of respirators and the components thereof for testing, in accordance with procedures set forth in Military Standard MIL-STD-414, 11 June 1957, including Change Notice No. 1, "Sampling Procedures and Tables for Inspection by Variables for Percent Defective," or an approved equivalent sampling procedure, or an approved combination of sampling procedures. The procedure of Military Standard MIL-STD-105D, 29 April 1963, "Sampling Procedures and Tables for Inspection by Attributes," is an example of an equivalent sampling procedure. MIL-STD-414 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from DODSSP, Standardization Document Order Desk, 700 Robbins Avenue, Bldg. 4D, Philadelphia, PA 19111-5094. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505-2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Copies of MIL-STD-105D may be inspected or obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505-2888. Incoming bulk raw material inspection or verification of specification, and in-process inspection shall be sufficient to ensure control of product quality through the manufacturing cycle.